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(54) Title: NOVEL POLYMORPHIC FORM OF IMATINIB MESYLATE AND A PROCESS FOR ITS PREPARATION

(57) Abstract: This invention discloses a novel stable crystal form of imatinib mesylate, designated by us as α_2 Form, which is stable at room temperature and even at higher temperatures upto 120 °C and accelerated stress conditions and, freely soluble in water. This invention also discloses a pharmaceutical composition containing the novel stable α_2 form of Imatinib mesylate and other usually employed excipients, useful in the treatment of Chronic Myelogenous Leukemia (CML). This new α_2 Form of imatinib mesylate is prepared by slurring Imatinib base in isopropanol at room temperature followed by addition of methane sulfonic acid and maintaining 50-60 °C followed by filtration. This invention also discloses another process for the preparation of the novel, stable α_2 crystalline form of Imatinib Mesylate by the conversion of Imatinib mesylate β -polymorphic modification by suspending it in water and organic solvents, distilling off water azeotropically, cooling and filtering to obtain the α_2 crystal form.



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